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EXAMINER

WOLLSCHLAGER, JEFFREY MICHAEL

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/921,192	Applicant(s) TURNER ET AL.	
	Examiner JEFFREY WOLLSCHLAGER	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8-20, 23-32, and 34-87 is/are pending in the application.
- 4a) Of the above claim(s) 12, 13, 27-30 and 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/22/08; 12/3/08</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Applicant's amendment to the claims filed November 13, 2008 has been entered.

Claims 1 and 87 are currently amended. Claims 4, 5, 7, 21, 22, and 33 have been canceled.

Claims 12, 13, 27-30 and 42-51 remain withdrawn from consideration. Claims 1-3, 6, 8-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415).

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Regarding claims 1 and 2, Winterton et al. teach a method for coating a contact lens comprising coating a mold with a polymeric material (Abstract; col. 1, lines 6-12; col. 3, line 55-col. 4, line 15; Example 5), such as poly(acrylic acid), poly(methacrylic acid), and poly(4-styrenesulfonic acid) (col. 10, lines 36-67), having a high molecular weight (col. 13, lines 55-65); dispensing a monomer mixture comprising a silicone containing hydrogel mixture into the coated mold (col. 4, lines 24-32; col. 18, lines 1-65; Nicolson et al., which is incorporated by reference into Winterton et al. at col. 4, lines 33-34: col. 9, line 35 and col. 7, line 54 showing the material has the required amount of water and is elastic such that it is properly considered a hydrogel monomer); and curing the monomer mixture and the coating to attach/entrap the coating composition to the contact lens (col. 4, lines 35-65; col. 22, line 66-col. 23, line 9). While Winterton et al. exemplify dispensing the monomer into the coated mold and curing as the immediate next step (col. 26, lines 9-14), implying a short dwell time (i.e., as set forth in the instant specification, the dwell time is the elapsed time from which the monomer mixture is dispensed into the mold until the curing commences), Winterton et al. do not exemplify that the dwell time is less than about 5 minutes.

However, Martin et al. disclose an automated method of producing contact lenses in a fast, efficient and precise manner (col. 3, lines 37-62) having a dwell time within the claimed range (col. 10, lines 60-67; col. 32, lines 28-41; col. 34, line 64-col. 35, line 15).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the contact lens coating method disclosed by Winterton et al. and to have employed the automated process disclosed by Martin et al., thereby yielding a dwell time within the claimed range, for the purpose, as suggested by Martin et al., of producing a contact lens in a fast, efficient and precise manner (Martin: col. 3, lines 37-62).

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Additionally, Winterton et al. suggest selecting the molecular weight of the material as a means of controlling coating thickness (col. 13, lines 55-58), thereby suggesting molecular weight is a result effective variable that would have been readily optimized. Winterton et al. do not teach the coating composition has a molecular weight of greater than about 300 kD. However, Vanderlaan et al. teach that hydrophilic coatings for contact lenses (col. 1, lines 12-25), including poly(acrylic acid) and poly(methacrylic acid), are suitably and preferably employed in a molecular weight range from about 100,000 to at least about 1,000,000 (col. 2, lines 23-38).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed a coating material with a molecular weight greater than about 300 kD, as suggested by Vanderlaan et al., since Winterton et al. suggest the molecular weight of the coating is a result effective variable for controlling the thickness of the coating that would have been readily optimized and Vanderlaan et al. suggest that the molecular weight for contact lens coatings such as poly(acrylic acid) and poly(methacrylic acid), two of the coatings employed by Winterton et al., are readily utilized at molecular weights ranging from about 100,000 to at least about 1,000,000.

As to the limitation directed to the coating polymer not chemically attaching to the article (e.g. it is physically adsorbed or entrapped/entangled), the examiner notes that Winterton et al. employ the same claimed coating composition and the same claimed silicone-containing hydrogel monomer and that the combination teaches the same claimed process. Accordingly, the examiner submits that it follows that the same claimed effects (e.g. coating material does not chemically attach to the contact lens) and physical properties would be realized by the teaching of the combined method. The examiner further notes that, similar to applicant,

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Winterton et al. do not employ additional materials such as coupling agents or mix crosslinking or co-reactive agents with the coating polymer. Further still, the examiner notes that Winterton et al. use language such as "attach" and "entrap" instead of "bond" when describing the coating process. As such, the examiner submits the attachment mechanism set forth in the combination is reasonably understood to be the same attachment mechanism set forth in the instant disclosure and as currently claimed.

As to claim 3, Winterton et al. suggest a large variety of hydrogel materials may be employed (col. 18, line 1- col. 21, line 67) and Nicholson et al., which is incorporated by reference into Winterton et al., suggest forming blends of hydrogel monomers (col. 7, lines 7-60).

As to claim 6, Martin et al. suggest a rapid and efficient process that minimizes dwell time, including a range of dwell times that are less than about 45 seconds (col. 10, lines 60-67; col. 32, lines 28-65; col. 34, line 64-col. 35, line 15). It would have been obvious to one having ordinary skill to have minimized the dwell time in the method of Winterton et al., as suggested by Martin et al., for the purpose of producing a contact lens in a fast, efficient and precise manner.

As to claim 8, Winterton et al. disclose that water (high boiling point) and alcohol (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having ordinary skill to have combined equivalents such as alcohol and water known to be suitable for the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

As to claims 52-54, Winterton et al. do not explicitly recite the viscosity of the coating composition. However, Winterton et al. do suggest controlling the molecular weight and further

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suggest dissolving the material in a solution at an appropriate concentration to control the coating thickness and to facilitate handling (col. 13, line 55 - col. 14, line 34). The examiner notes that both the molecular weight and the amount of solvent employed impact the viscosity of the material. As such, and as suggested by Winterton et al., the examiner submits one having ordinary skill in the art would have readily optimized the molecular weight within the range set forth by Winterton et al. and would have readily optimized the amount of solvent, which accordingly adjusts the viscosity, for the purpose of producing a desired coating thickness while ensuring non-difficult handling of the material.

As to claims 56-59, 61 and 62, Winterton et al. disclose that water (high boiling point) and alcohol, such as ethanol, (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having ordinary skill to have combined equivalents such as alcohol and water known to be suitable for the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415), as applied to claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 above, and further in view of Li et al. (US 6,565,776).

As to claim 9, the combination teaches the method set forth above. While Winterton et al. teach that any technique for applying a coating may be employed (col. 15, lines 33-35), they do not teach spin coating. However, Li et al. teach that spin coating is a recognized suitable and effective technique for coating a contact lens mold (col. 6, lines 42-62).

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Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed a spin coating technique as suggested by Li et al. for the purpose, as suggested by Li et al., of effectively coating the mold in an art recognized suitable manner.

As to claim 10, Winterton et al. suggest coating a contact lens mold to achieve a desired coating thickness. The examiner submits that one having ordinary skill would have readily optimized and determined the amount of material required to coat the mold to achieve the desired extent and thickness of coating.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415) and Li et al. (US 6,565,776), as applied to claims 9 and 10 above, and further in view of Soye et al. (US 5,316,700).

As to claim 11, the combination of claim 10 teaches the method set forth above. Winterton et al. do not teach applying pressurized air to an edge of the mold. However, Soye et al. disclose a method of removing excess material by applying pressurized air to an edge of a contact lens mold (Figure 5; col. 3, line 67-col. 4, line 2).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed pressurized air to the contact lens mold as suggested by Soye et al, for the purpose, as suggested by Soye et al., of removing excess lens forming material.

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Claims 14-18, 23, 64-66, 68-71, 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Yang et al. (US 5,397,848) and Lohmann et al. (US 6,169,127).

Regarding claims 14 and 15, Winterton et al. teach a method for coating a contact lens comprising coating a mold with a polymeric material (Abstract; col. 1, lines 6-12; col. 3, line 55-col. 4, line 15; Example 5), such as poly(acrylic acid), poly(methacrylic acid), and poly(4-styrenesulfonic acid) (col. 10, lines 36-67), having a high molecular weight (col. 13, lines 55-65); dispensing a monomer mixture comprising a silicone containing hydrogel mixture into the coated mold (col. 4, lines 24-32; col. 18, lines 1-65; Nicolson et al., which is incorporated by reference into Winterton et al. at col. 4, lines 33-34: col. 9, line 35 and col. 7, line 54 showing the material has the required amount of water and is elastic such that it is properly considered a hydrogel monomer); and curing the monomer mixture and the coating to attach/entrap the coating composition to the contact lens (col. 4, lines 35-65; col. 22, line 66-col. 23, line 9). While Winterton et al. exemplify dispensing the monomer into the coated mold and curing as the immediate next step (col. 26, lines 9-14), implying a short dwell time (i.e., as set forth in the instant specification, the dwell time is the elapsed time from which the monomer mixture is dispensed into the mold until the curing commences), Winterton et al. do not exemplify that the dwell time is less than about 5 minutes or that the coating composition comprises poly(2-hydroxyethyl methacrylate).

However, Martin et al. disclose an automated method of producing contact lenses in a fast, efficient and precise manner (col. 3, lines 37-62) having a dwell time within the claimed range (col. 10, lines 60-67; col. 32, lines 28-41; col. 34, line 64-col. 35, line 15). Additionally, Yang et al. teach that when treating silicone based polymeric lens materials, poly(acrylic acid),

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poly(methacrylic acid), and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials (Abstract; col. 1, lines 18-24; col. 9, lines 18-32) and Lohmann et al. (Abstract; col. 16, line 9; col. 23, lines 1-4) provide evidence that in the art of producing contact lenses, poly(2-hydroxyethyl methacrylate) is generally referred to as poly(hydroxyethyl methacrylate), as this is the conventional form of the material employed in the art (i.e. as opposed to the only other alternative: poly(1-hydroxyethyl methacrylate)).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the contact lens coating method disclosed by Winterton et al. and to have employed the automated process disclosed by Martin et al., thereby yielding a dwell time within the claimed range, for the purpose, as suggested by Martin et al., of producing a contact lens in a fast, efficient and precise manner (Martin: col. 3, lines 37-62). Additionally, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have replaced the poly(acrylic acid) or poly(methacrylic acid) hydrophilic coating materials with poly(2-hydroxyethyl methacrylate), as suggested by Yang et al. and Lohmann et al., since Yang et al. suggest poly(acrylic acid), poly(methacrylic acid), and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials known in the art (MPEP 2144.06-2144.07) and Lohmann et al. teach and suggest that poly(2-hydroxyethyl methacrylate) is specifically suited as a coating material and is generally referred to as poly(hydroxyethyl methacrylate) in the contact lens art.

As to the limitation directed to the coating polymer not chemically attaching to the article (e.g. it is physically adsorbed or entrapped/entangled), the examiner notes that Winterton et al. employ the same claimed coating composition and the same claimed silicone-containing hydrogel monomer and that the combination teaches the same claimed process. Accordingly,

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the examiner submits that it follows that the same claimed effects (e.g. coating material does not chemically attach to the contact lens) and physical properties would be realized by the teaching of the combined method. The examiner further notes that, similar to applicant, Winterton et al. do not employ additional materials such as coupling agents or mix crosslinking or co-reactive agents with the coating polymer. Further still, the examiner notes that Winterton et al. use language such as "attach" and "entrap" instead of "bond" when describing the coating process. As such, the examiner submits the attachment mechanism set forth in the combination is reasonably understood to be the same attachment mechanism set forth in the instant disclosure and as currently claimed.

As to claims 16 and 17, Winterton et al. suggest a large variety of hydrogel materials may be employed (col. 18, line 1- col. 21, line 67) and Nicholson et al., which is incorporated by reference into Winterton et al., suggest forming blends of hydrogel monomers (col. 7, lines 7-60). Further, Winterton et al. employ a silicone containing hydrogel mixture (col. 4, lines 24-32; col. 18, lines 1-65; Nicholson et al., which is incorporated by reference into Winterton et al. at col. 4, lines 33-34; col. 9, line 35 and col. 7, line 54 showing the material has the required amount of water and is elastic such that it is properly considered a hydrogel monomer).

As to claim 18, Martin et al. disclose a dwell time that overlaps with the claimed less than about 45 second dwell time (col. 10, lines 60-67; col. 32, lines 28-41; col. 34, line 64-col. 35, line 15; response to arguments below). It would have been obvious to one having ordinary skill to have minimized the dwell time in the method of Winterton et al., as suggested by Martin et al., for the purpose of producing a contact lens in a fast, efficient and precise manner.

As to claim 23, Winterton et al. disclose that water (high boiling point) and alcohol (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having

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ordinary skill to have combined equivalents such as alcohol and water known to be suitable for the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

As to claims 64-66, Winterton et al. do not explicitly recite the viscosity of the coating composition. However, Winterton et al. do suggest controlling the molecular weight and further suggest dissolving the material in a solution at an appropriate concentration to control the coating thickness and to facilitate handling (col. 13, line 55 - col. 14, line 34). The examiner notes that both the molecular weight and the amount of solvent employed impact the viscosity of the material. As such, and as suggested by Winterton et al., the examiner submits one having ordinary skill in the art would have readily optimized the molecular weight within the range set forth by Winterton et al. and would have readily optimized the amount of solvent, which accordingly adjusts the viscosity, for the purpose of producing a desired coating thickness while ensuring non-difficult handling of the material.

As to claims 68-71, 73 and 74, Winterton et al. disclose that water (high boiling point) and alcohol, such as ethanol, (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having ordinary skill to have combined equivalents such as alcohol and water known to be suitable for the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Yang et al. (US 5,397,848)

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and Lohmann et al. (US 6,169,127), as applied to claims 14-18, 23, 64-66, 68-71, 73 and 74 above, and further in view of Turner et al. (WO 01/27662).

As to claims 19 and 20, the combination teaches the method set forth above. Winterton et al. do not teach the silicone hydrogel monomer as claimed. However, Turner et al. disclose a method of making contact lenses having desired physiological performance employing silicone hydrogel monomer meeting the claim (page 4, line 18 - page 6, line 25; Examples 3, 4 and 5).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed the silicone hydrogel monomer as suggested by Turner et al. since Turner et al. suggest the compositions provides a lens having desired physiological performance.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Yang et al. (US 5,397,848) and Lohmann et al. (US 6,169,127), as applied to claims 14-18, 23, 64-66, 68-71, 73 and 74 above, and further in view of Li et al. (US 6,565,776).

As to claim 24, the combination teaches the method set forth above. While Winterton et al. teach that any technique for applying a coating may be employed (col. 15, lines 33-35), they do not teach spin coating. However Li et al. teach that spin coating is a recognized suitable and effective technique for coating a contact lens mold (col. 6, lines 42-62).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed a spin coating technique as suggested by Li et al. for the purpose, as suggested by Li et al., of effectively coating the mold in an art recognized suitable manner.

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As to claim 25, Winterton et al. suggest coating a contact lens mold to achieve a desired coating thickness. The examiner submits that one having ordinary skill would have readily optimized and determined the amount of material required to coat the mold to achieve the desired extent and thickness of coating.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Yang et al. (US 5,397,848) and Lohmann et al. (US 6,169,127), and further in view of Li et al. (US 6,565,776), as applied to claims 24 and 25 above, and further in view of Soye et al. (US 5,316,700).

As to claim 26, the combination of claim 10 teaches the method set forth above. Winterton et al. do not teach applying pressurized air to an edge of the mold. However, Soye et al. disclose a method of removing excess material by applying pressurized air to an edge of a contact lens mold (Figure 5; col. 3, line 67-col. 4, line 2).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed pressurized air to the contact lens mold as suggested by Soye et al, for the purpose, as suggested by Soye et al. of removing excess lens forming material.

Claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415).

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Regarding claim 31, Winterton et al. teach a method for coating a contact lens comprising coating a mold with a polymeric material (Abstract; col. 1, lines 6-12; col. 3, line 55-col. 4, line 15; Example 5), such as poly(acrylic acid), poly(methacrylic acid), and poly(4-styrenesulfonic acid) (col. 10, lines 36-67); dispensing a monomer mixture comprising a silicone containing hydrogel mixture into the coated mold (col. 4, lines 24-32; col. 18, lines 1-65; Nicolson et al., which is incorporated by reference into Winterton et al. at col. 4, lines 33-34; col. 9, line 35 and col. 7, line 54 showing the material has the required amount of water and is elastic such that it is properly considered a hydrogel monomer); and curing the monomer mixture and the coating to attach/entrap the coating composition to the contact lens (col. 4, lines 35-65; col. 22, line 66-col. 23, line 9). While Winterton et al. exemplify dispensing the monomer into the coated mold and curing as the immediate next step (col. 26, lines 9-14), implying a short dwell time (i.e., as set forth in the instant specification, the dwell time is the elapsed time from which the monomer mixture is dispensed into the mold until the curing commences), Winterton et al. do not exemplify that the dwell time is less than about 45 seconds. Further, while Winterton et al. suggest selecting the molecular weight of the material as a means of controlling coating thickness (col. 13, lines 55-58), thereby suggesting molecular weight is a result effective variable that would have been readily optimized, Winterton et al. do not teach the coating composition has a molecular weight of greater than about 300 kD.

However, Martin et al. disclose an automated method of producing contact lenses in a fast, efficient and precise manner (col. 3, lines 37-62) having a dwell time that overlaps with the claimed range (col. 10, lines 60-67; col. 32, lines 28-41; col. 34, line 64-col. 35, line 15). Additionally, Vanderlaan et al. teach that hydrophilic coatings for contact lenses (col. 1, lines 12-25), including poly(acrylic acid) and poly(methacrylic acid), are suitably and preferably employed in a molecular weight range from about 100,000 to at least about 1,000,000 (col. 2, lines 23-38).

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Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the contact lens coating method disclosed by Winterton et al. and to have employed the automated process disclosed by Martin et al., thereby yielding a dwell time within the claimed range, for the purpose, as suggested by Martin et al., of producing a contact lens in a fast, efficient and precise manner (Martin: col. 3, lines 37-62).

Additionally, it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed a coating material with a molecular weight greater than about 300 kD, as suggested by Vanderlaan et al., since Winterton et al. suggest the molecular weight of the coating is a result effective variable for controlling the thickness of the coating that would have been readily optimized and Vanderlaan et al. suggest that the molecular weight for contact lens coatings such as poly(acrylic acid) and poly(methacrylic acid), two of the coatings employed by Winterton et al., are readily utilized at molecular weights ranging from about 100,000 to at least about 1,000,000.

As to claim 32, Winterton et al. suggest a large variety of hydrogel materials may be employed (col. 18, line 1- col. 21, line 67) and Nicholson et al., which is incorporated by reference into Winterton et al., suggest forming blends of hydrogel monomers (col. 7, lines 7-60).

As to claim 36, Winterton et al. employ poly(acrylic acid) and poly(methacrylic acid) (col. 10, lines 36-67).

As to claim 38, Winterton et al. disclose that water (high boiling point) and alcohol (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having ordinary skill to have combined equivalents such as alcohol and water known to be suitable for

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the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

As to claims 76-78, Winterton et al. do not explicitly recite the viscosity of the coating composition. However, Winterton et al. do suggest controlling the molecular weight and further suggest dissolving the material in a solution at an appropriate concentration to control the coating thickness and to facilitate handling (col. 13, line 55 - col. 14, line 34). The examiner notes that both the molecular weight and the amount of solvent employed impact the viscosity of the material. As such, and as suggested by Winterton et al., the examiner submits one having ordinary skill in the art would have readily optimized the molecular weight within the range set forth by Winterton et al. and would have readily optimized the amount of solvent, which accordingly adjusts the viscosity, for the purpose of producing a desired coating thickness while ensuring non-difficult handling of the material.

As to claims 80-83, 85 and 86, Winterton et al. disclose that water (high boiling point) and alcohol, such as ethanol, (low boiling point) solvents may be employed (col. 14, lines 1-22), and exemplify utilizing isopropyl alcohol and water together (col. 23, lines 35-40). It would have been obvious to one having ordinary skill to have combined equivalents such as alcohol and water known to be suitable for the same purpose in the method of Winterton et al. in order to form a third composition for the very same purpose (MPEP 2144.06).

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415), as applied to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 above, and further in view of Turner et al. (WO 01/127662).

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As to claims 34 and 35, the combination teaches the method set forth above. Winterton et al. do not teach the silicone hydrogel monomer as claimed. However, Turner et al. disclose a method of making contact lenses having desired physiological performance employing silicone hydrogel monomer meeting the claim (page 4, line 18 - page 6, line 25; Examples 3, 4 and 5).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed the silicone hydrogel monomer as suggested by Turner et al. since Turner et al. suggest the compositions provides a lens having desired physiological performance.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415), as applied to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 above, and further in view of Yang et al. (US 5,397,848) and Holguin et al. (US 6,706,836).

As to claim 37, the combination teaches the method set forth above. Winterton et al. do not teach employment of poly(2-hydroxyethyl methacrylate). However, Yang et al. teach that when treating silicone based polymeric lens materials, poly(acrylic acid), poly(methacrylic acid), and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials (Abstract; col. 1, lines 18-24; col. 9, lines 18-32) and Holguin et al. teach a method of producing gel-free poly(2-hydroxyethyl methacrylate) coatings (Abstract; col. 1, lines 6-28) having a molecular weight ranging from 176,000 to about 1,000,000 (col. 14, lines 7-10).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed poly(2-hydroxyethyl methacrylate) as the coating composition since Yang et al.

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suggest poly(acrylic acid), poly(methacrylic acid), and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials known in the art (MPEP 2144.06-2144.07) and Holguin et al. teach poly(2-hydroxyethyl methacrylate) having a molecular weight ranging from 176,000 to 1,000,000 that provides a gel free coating material.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415), as applied to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 above, and further in view of Li et al. (US 6,565,776).

As to claim 39, the combination teaches the method set forth above. While Winterton et al. teach that any technique for applying a coating may be employed (col. 15, lines 33-35), they do not teach spin coating. However Li et al. teach that spin coating is a recognized suitable and effective technique for coating a contact lens mold (col. 6, lines 42-62).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed a spin coating technique as suggested by Li et al. for the purpose, as suggested by Li et al., of effectively coating the mold in an art recognized suitable manner.

As to claim 40, Winterton et al. suggest coating a contact lens mold to achieve a desired coating thickness. The examiner submits that one having ordinary skill would have readily optimized and determined the amount of material required to coat the mold to achieve the desired extent and thickness of coating.

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Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US 6,087,415) and Li et al. (US 6,565,776), as applied to claims 39 and 40 above, and further in view of Soye et al. (US 5,316,700).

As to claim 41, the combination of claim 10 teaches the method set forth above. Winterton et al. do not teach applying pressurized air to an edge of the mold. However, Soye et al. disclose a method of removing excess material by applying pressurized air to an edge of a contact lens mold (Figure 5; col. 3, line 67-col. 4, line 2).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed pressurized air to the contact lens mold as suggested by Soye et al, for the purpose, as suggested by Soye et al. of removing excess lens forming material.

Claims 55, 60 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899), as applied to claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 above, and further in view of Narducy et al. (US 4,963,159).

As to claims 55, 60 and 63, the combination teaches the method set forth above. Further, Winterton et al. teach that a variety of solvents may be employed (col. 14, lines 1-22). Winterton et al. do not teach employment of ethanol and ethyl lactate. However, Narducy et al. teach a method of making hydrophilic contact lenses wherein they teach ethanol as a solvent and ethyl lactate as a suitable co-solvent (Abstract; col. 5, lines 10-24).

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Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed ethanol as a solvent and ethyl lactate as a co-solvent since Narducy et al. teach that such a combination of solvents is known to be suitable in the art of producing contact lenses.

Claims 67, 72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Yang et al. (US 5,397,848) and Lohmann et al. (US 6,169,127), as applied to claims 14-18, 23, 64-66, 68-71, 73 and 74 above, and further in view of Narducy et al. (US 4,963,159).

As to claims 67, 72 and 75, the combination teaches the method set forth above. Further, Winterton et al. teach that a variety of solvents may be employed (col. 14, lines 1-22). Winterton et al. do not teach employment of ethanol and ethyl lactate. However, Narducy et al. teach a method of making hydrophilic contact lenses wherein they teach ethanol as a solvent and ethyl lactate as a suitable co-solvent (Abstract; col. 5, lines 10-24).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed ethanol as a solvent and ethyl lactate as a co-solvent since Narducy et al. teach that such a combination of solvents is known to be suitable in the art of producing contact lenses.

Claims 79, 84 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929), which incorporates Nicolson et al. (US 5,760,100) into the disclosure by reference, in view of Martin et al. (US 6,039,899) and Vanderlaan et al. (US

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6,087,415), as applied to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 above, and further in view of Narducy et al. (US 4,963,159).

As to claims 79, 84 and 87, the combination teaches the method set forth above. Further, Winterton et al. teach that a variety of solvents may be employed (col. 14, lines 1-22). Winterton et al. do not teach employment of ethanol and ethyl lactate. However, Narducy et al. teach a method of making hydrophilic contact lenses wherein they teach ethanol as a solvent and ethyl lactate as a suitable co-solvent (Abstract; col. 5, lines 10-24). Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the method of Winterton et al. and to have employed ethanol as a solvent and ethyl lactate as a co-solvent since Narducy et al. teach that such a combination of solvents is known to be suitable in the art of producing contact lenses.

Response to Arguments

Applicant's arguments filed November 13, 2008 have been fully considered, but they are not persuasive. The examiner initially notes that the amendment to claim 1 incorporates the subject matter of previous claim 5. As such, and in accord with the arguments, the examiner responds to the arguments from the starting point of the rejection of previous claim 5.

Applicant argues that Winterton et al. teach away from employing coating materials having molecular weights greater than 150,000 to avoid difficulty in handling. This argument is not persuasive. The examiner submits that Winterton et al. make it clear that there is a direct correlation to the molecular weight of the coating materials to be employed and the thickness of the coating to be achieved. As such, Winterton et al. have established the molecular weight of the coating as a result effective variable used to control the thickness of the coating and such a molecular weight would have been optimized to achieve a desired coating thickness and final

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coating properties. While Winterton et al. do teach that "typically" the upper limit of the molecular weight will be "about 150,000" this is by no means taught by Winterton et al. as being the upper limit above which one can not go. The examiner further notes that Winterton et al. teach that if the "increase in molecular weight is too substantial, the difficulty in handling may also increase". The examiner submits this is not a teaching away from utilizing molecular weights greater than 150,000 and that Winterton et al. merely state a basic polymer fact - higher molecular weight polymers are more difficult to handle than lower molecular weight polymers (e.g. Melt Flow Rate is lower/viscosity is higher in higher molecular weight polymers of the same type). Additionally, when taken with the molecular weight ranges disclosed by Vanderlaan et al. as being suitable for forming a coating on a contact lens (10,000 to 10,000,000) the examiner submits that 300 kD is not even clearly "too substantial[ly]" higher than 150,000. The examiner submits that in view of the combination one having ordinary skill would have had a predictable and clearly reasonable expectation of success when employing molecular weights greater than 150,000, including values greater than 300 kD, in the method of Winterton et al. One having ordinary skill in the art would have selected the molecular weight of the coating polymer in order to achieve the intended final properties of the coating and would not have understood the teaching of Winterton et al. to teach away from utilizing polymers with a molecular weight greater than 150,000.

Applicant's arguments regarding the Martin et al. reference have been fully considered, but they are not persuasive. Applicant argues that certain claims require a dwell time of less than about 45 seconds and argue that Miller teach the lenses may be held in the accumulator from between 72 and 144 seconds. This argument is not persuasive. As an initial matter, the examiner notes that claim 1 only requires a dwell time of less than 5 minutes. The examiner notes that applicant's recited timeframe takes the maximum number of lenses suggested by

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Martin et al. into account ("up to ninety-six (96)"). In this "up-to" embodiment, about half of the lenses would continue to have a dwell time of less than about 45 seconds. As such, the examiner submits that Martin et al. clearly teach a dwell time of less than 5 minutes as set forth in independent claims 1 and 14 and teach at least an overlapping range of dwell times of less than about 45 seconds as set forth in claims 6, 7, 18, 31 and 32-41 in this "up-to" embodiment. Applicant further argues that the Martin reference requires twelve pallets and as such the examiner's utilization of "up to" as set forth above is not completely accurate. This argument is not persuasive. The examiner maintains that, while he understands how applicant is reading the sentence, he submits that it is equally appropriate to interpret the argued sentence to suggest that the number of molds/pallet are the same and that the suggestion of the sentence is to control the number of pallets to thereby ultimately achieve a desired number of molds. However, importantly, in either interpretation, the examiner maintains that a substantial portion of the molds continue to have a dwell time of less than 45 seconds (for example, the last pallet would have a dwell time of approximately 6-12 seconds) and that, as such, Martin et al. at least teach an overlapping range of dwell times with the claimed range. Applicant's arguments also appear to suggest there are new and/or unexpected results with the claimed dwell time of less than 45 seconds. However, the examiner notes that there is no evidence on the record to support the argument and further notes that claim 1 allows for dwell times up to 5 minutes.

Applicant argues that Yang et al. is not properly combinable with Winterton et al. because Winterton et al. is directed to polyionic coatings and Yang et al. is directed to forming hydrophilic-silicone co-polymers. This argument is not persuasive. As an initial matter, the examiner notes that Winterton et al. and Yang et al. each disclose that the purpose for employing the chemicals they employ is to improve the hydrophilicity of the contact lens. Winterton et al. teach that polyacrylic acid and polymethacrylic acid are among these hydrophilic

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enhancing chemicals. Similarly, Yang et al. teach that polyacrylic acid, polymethacrylic acid, and polyhydroxyethyl methacrylate are among these hydrophilic enhancing chemicals “which have been characterized as polyelectrolytes”. Further, Yang et al. suggest that mixtures of these chemicals can be employed and Winterton et al. suggest that other materials and additives may be employed with their coatings. The examiner maintains that the combination suggests that polyacrylic acid, polymethacrylic acid, and polyhydroxyethyl methacrylate are art recognized equivalents known to be suitable in the art for improving the hydrophilic nature of contact lenses (MPEP 2144.06-2144.07) and as such the combination presents a *prima facie* case of obviousness. Additionally, the examiner notes that the Lohman et al. reference has been applied for the teaching and suggestion that poly(2-hydroxyethyl methacrylate) is specifically suited for use as a coating material and is generally referred to as poly(hydroxyethyl methacrylate) in the contact lens art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY WOLLSCHLAGER whose telephone number is (571)272-8937. The examiner can normally be reached on Monday - Thursday 6:45 - 4:15, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. W./
Examiner, Art Unit 1791

January 28, 2009

/Monica A Huson/
Primary Examiner, Art Unit 1791